listing of the claims, which will replace all prior versions, and listings, of claims in the application:

1 – 18. (Cancelled)

19. (Currently Amended) A non-human transgenic mammal selected from the group consisting of mice, rats, goats, pigs, sheep and cows, whose genome comprises:

(a) an α-lactalbumin (α-LA) promoter; and

(b) a nucleotide sequence liked to the α-LA promoter, the nucleotide sequence encoding a recombinant polypeptide comprising ~~a milk species signal peptide~~ a bovine α-S1 casein signal peptide of SEQ ID NO:14, and a recombinant mature human clotting factor VIII (FVIII) polypeptide of a B-domain deleted human clotting factor VIII (FVIII) polypeptide having a recombinant spliced site, Ser 741 link to Leu 1643,

wherein the non-human transgenic mammal secretes the recombinant B-domain deleted human FVIII polypeptide in milk when the mammal is lactating.

20. – 22. (Cancelled)

23. (Currently Amended) The non-human transgenic mammal of claim ~~22~~ 19, wherein the bovine α-S1 casein signal peptide is encoded by the DNA sequence of SEQ ID NO: 2.

24. (Currently Amended) The non-human transgenic mammal of claim ~~22~~ 19, wherein the recombinant polypeptide comprises the amino acid sequence of SEQ ID NO: 15.

25. (Previously presented) The non-human transgenic mammal of claim 19, wherein the B-domain deleted human FVIII polypeptide is proteolytically processed intracellularly into a light chain having the A3, C1 and C2 domains and a heavy chain having the A1 and A2 domains, wherein the light chain and heavy chain are operably linked by a junction.

26. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the α-LA promoter is a 2.0-kb bovine α-LA promoter.

27. (Currently Amended) The non-human transgenic mammal of claim 19, ~~producing~~ wherein the transgenic mammal secretes up to ~~about~~ 50 mg of the B-domain deleted human FVIII polypeptide per liter of milk when the non-human transgenic mammal is lactating.

28. (Currently Amended) A method for making the non-human transgenic mammal of claim 1, the method comprising:

(a) introducing into an embryo of a <u>non-human</u> mammal a transgene comprising

(i) ~~the~~ <u>an</u> α-lactalbumin (α-LA) promoter; and

(ii) ~~the~~ <u>a</u> nucleotide sequence liked to the α-LA promoter, <u>the nucleotide sequence encoding a recombinant polypeptide comprising a bovine α-S1 casein signal peptide of SEQ ID NO:14, and a recombinant mature human clotting factor VIII (FVIII) polypeptide of a B-domain deleted human clotting factor VIII (FVIII) polypeptide having a recombinant spliced site, Ser 741 link to Leu 1643,</u>

(b) implanting the embryo into a female of the same species as the embryo; and

(c) permitting the embryo to develop into the non-human transgenic mammal of claim 1.

29. (Previously Presented) The method of claim 28, further comprising confirming the presence of the transgene in the non-human transgenic mammal by polymerase chain reaction (PCR) analysis.

30. (Previously Presented) The method of claim 28, further comprising confirming the expression of the transgene in the non-human transgenic mammal by reverse transcription PCR analysis.

31. (Previously Presented) The method of claim 28, further comprising analyzing milk from the non-human transgenic mammal for the B-domain deleted human FVIII polypeptide.

32. (Previously Presented, Withdrawn) Milk collected from the non-human transgenic mammal of claim 19, wherein the milk comprises the recombinant human FVIII polypeptide.

33. (Previously Presented, Withdrawn) Milk collected from the non-human transgenic mammal of claim 22, wherein the milk comprises the recombinant human FVIII polypeptide.

34. (Currently Amended, Withdrawn) The milk of claim 32, comprising up to ~~about~~ 50 mg of the B-domain deleted human FVIII polypeptide per ~~litter~~ <u>liter</u> of the milk.

35. and 36. (Cancelled)

37. (New, Withdrawn) The milk of claim 33, comprising up to 50 mg of the B-domain deleted human FVIII polypeptide per liter of the milk.